

Claims

1. A composition comprising tiotropium, or a pharmaceutically acceptable salt or hydrate thereof, an HFC propellant, a solvent, and an acid selected from the group consisting of one or more of inorganic and organic acids having a pH range of 2.5 - 4.5 in aqueous solution.
2. The composition according to claim 1 comprising 0.00008 to 0.4 % by weight tiotropium, or a pharmaceutically acceptable salt or hydrate thereof.
3. The composition according to claim 2, wherein the pharmaceutically acceptable salt of tiotropium is selected from the group consisting of one or more of chloride, bromide, iodide, methanesulphonate or para-toluenesulphonate.
4. The composition according to claim 1 wherein the HFC propellant is selected from the group consisting of HFC-134(a), HFC-227, HFC-32, HFC-143(a), HFC-134, HFC-152a, and mixtures thereof.
5. The composition according to claim 1 wherein the acid is selected from the group of inorganic acids consisting of hydrochloric acid, sulfuric acid, nitric acid, and phosphoric acid.
6. The composition according to claim 1 wherein the acid is selected from the group of organic acids consisting of ascorbic acid, citric acid, lactic acid, malic acid, benzoic acid, and tartaric acid.
7. The composition according to claim 1 further comprising water in an amount of up to about 5% by weight.
8. The composition according to claim 1 wherein the solvent is selected from the group consisting of one or more of alcohols, glycols, glycol ethers, block copolymers of oxyethylene and oxypropylene, glycerol, polyoxyethylene alcohols, polyoxetethylene fatty acid esters and glycofurols.

9. The composition according to claim 8 wherein the solvent is present in an amount in the range of 5 - 50% by weight.
10. The composition according to claim 1 comprising an anhydrous crystalline form of
5 tiotropium bromide.
11. The composition according to claim 1 that is free of water.
12. The composition according to claim 10 that is free of water.
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13. The composition according to claim 2 comprising tiotropium bromide monohydrate in a range of from 0.0001% to 0.5% (by weight), ethanol in the range of 5% to 50% (by weight), water up to 5% (by weight), acid in an amount to yield a pH range of 2.5 to 4.5 in aqueous solution, and an HFC propellant.
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14. The composition according to claim 10 comprising anhydrous crystalline tiotropium bromide in the range of 0.0001% to 0.5% (by weight), ethanol in the range of 5% to 50% (by weight), water up to 5% (by weight), acid in an amount to yield a pH range of 2.5 to 4.5 in aqueous solution, and an HFC propellant.
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15. A device for the administration of aerosol compositions comprising the composition according to claim 1.
16. A device for the administration of aerosol compositions comprising the composition
25 according to claim 10.
17. A device for the administration of aerosol compositions comprising the composition according to claim 13.
- 30 18. A device for the administration of aerosol compositions comprising the composition according to claim 14.
19. The device according to claim 15 in the form of a metered-dose inhaler.
- 35 20. The composition according to claim 1 in the form of an aerosol solution formulation.